#### Message

From: Cyran, Carissa [Cyran.Carissa@epa.gov]

**Sent**: 8/25/2021 2:51:46 PM

To: Lowit, Anna [Lowit.Anna@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov];

Friedman, Dana [Friedman.Dana@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Kiely, Timothy

[Kiely.Timothy@epa.gov]

CC: Metzger, Michael [Metzger.Michael@epa.gov]; Feitel, Alexandra [feitel.alexandra@epa.gov]; Pyne, Jaclyn

[Pyne.Jaclyn@epa.gov]

Subject: Re: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Thank you for your assistance and quick reviews on the draft language, below is the final response. OCSPP IO sent forward the initial language.

### **RESPONSE:**

EPA's final rule for chlorpyrifos issued last week was in response to the April 29, 2021 <u>decision</u> of the United States Court of Appeals for the Ninth Circuit. The Ninth Circuity gave EPA 60 days to issue a final rule in which the agency either modified the chlorpyrifos tolerances and issue a finding that the modified tolerances are safe, or revoked the <u>tolerances</u>.

At this time, EPA can't conclude that aggregate exposure to chlorpyrifos meets the legally required safety standard of reasonable certainty of no harm. While the agency has sought to better quantify the potential neurodevelopmental effects associated with chlorpyrifos exposure over the past decade, these efforts ultimately were not concluded. However, that does not alleviate the Agency's concerns regarding these potential neurodevelopmental effects. The agency will continue to evaluate recent developments in the science around chlorpyrifos and neurodevelopmental effects, including the conclusions of the 2020 FIFRA SAP on New Approach Methods.

EPA sought to verify the conclusions of the epidemiology studies (Rauh et. al) conducted by Columbia University. EPA remains unable to verify the reported findings of the Columbia Center for Children's Environmental Health (CCCEH) papers or conduct alternative statistical analyses to evaluate the findings. The 2016 FIFRA Scientific Advisory Panel (SAP) did not support the "direct use" of the cord blood and working memory data for deriving the regulatory endpoint due in part to insufficient information about timing and magnitude of chlorpyrifos applications in relation to cord blood concentrations at the time of birth, uncertainties about the prenatal window(s) of exposure linked to reported effects, lack of a second laboratory to reproduce the analytical blood concentrations and lack of raw data from the epidemiology study.

In 2016, after receiving public comments on the 2014 risk assessment and feedback from the 2016 FIFRA SAP, EPA <u>revised its human health risk assessment</u> for chlorpyrifos, which was published subsequent to the issuance of the proposed rule, and retained the 10X the Food Quality Protection Act (FQPA) safety factor (SF). The proposed rule and revised human health risk assessment did not go through FIFRA SAP review.

From: Lowit, Anna <Lowit.Anna@epa.gov>

**Sent:** Tuesday, August 24, 2021 1:42 PM

**To:** Vogel, Dana < Vogel. Dana@epa.gov>; Reaves, Elissa < Reaves. Elissa@epa.gov>; Cyran, Carissa < Cyran. Carissa@epa.gov>; Friedman, Dana < Friedman. Dana@epa.gov>; Wilbur, Donald < Wilbur. Donald@epa.gov>; Kiely, Timothy < Kiely. Timothy@epa.gov>

**Cc:** Metzger, Michael <Metzger.Michael@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>

Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Agree with Elissa and Dana V

From: Vogel, Dana < Vogel.Dana@epa.gov> Sent: Tuesday, August 24, 2021 12:42 PM

**To:** Reaves, Elissa <Reaves.Elissa@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>

**Cc:** Metzger, Michael <Metzger.Michael@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>

Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

I agree with Elissa and prefer the previous version.

From: Reaves, Elissa < Reaves. Elissa@epa.gov>

**Sent:** Tuesday, August 24, 2021 12:38 PM

**To:** Cyran, Carissa < Cyran.Carissa@epa.gov>; Friedman, Dana < Friedman.Dana@epa.gov>; Lowit, Anna < Lowit.Anna@epa.gov>; Vogel, Dana < Vogel.Dana@epa.gov>; Wilbur, Donald < Wilbur.Donald@epa.gov>; Kiely, Timothy < Kiely.Timothy@epa.gov>

**Cc:** Metzger, Michael < Metzger.Michael@epa.gov >; Feitel, Alexandra < feitel.alexandra@epa.gov >; Pyne, Jaclyn < Pyne.Jaclyn@epa.gov >

Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
703-305-0312

From: Cyran, Carissa < Cyran.Carissa@epa.gov >

**Sent:** Tuesday, August 24, 2021 12:28 PM

**To:** Friedman, Dana < Friedman.Dana@epa.gov>; Lowit, Anna < Lowit.Anna@epa.gov>; Vogel, Dana < Vogel.Dana@epa.gov>; Wilbur, Donald < Wilbur.Donald@epa.gov>; Reaves, Elissa < Reaves.Elissa@epa.gov>; Kiely, Timothy < Kiely.Timothy@epa.gov>

**Cc:** Metzger, Michael < Metzger.Michael@epa.gov>; Feitel, Alexandra < feitel.alexandra@epa.gov>; Pyne, Jaclyn < Pyne.Jaclyn@epa.gov>

Subject: Re: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Importance: High

Michal had a few suggested edits. Is PRD and HED ok with the revised response? Thank you!

Response:

## Ex. 5 Deliberative Process (DP)

### Ex. 5 Deliberative Process (DP)

From: Cyran, Carissa < Cyran. Carissa@epa.gov> **Sent:** Tuesday, August 24, 2021 11:20 AM

To: Friedman, Dana <Friedman.Dana@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Vogel, Dana

<Vogel.Dana@epa.gov>; Wilbur, Donald <Wilbur.Donald@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely,

Timothy <Kiely.Timothy@epa.gov>

Cc: Metzger, Michael < Metzger.Michael@epa.gov >; Feitel, Alexandra < feitel.alexandra@epa.gov >; Pyne, Jaclyn

<Pyne.Jaclyn@epa.gov>

Subject: Re: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Thank you. We removed that language and sent the resposne to OPP IO.

From: Friedman, Dana < Friedman. Dana@epa.gov>

Sent: Tuesday, August 24, 2021 11:14 AM

To: Lowit, Anna <Lowit. Anna@epa.gov>; Cyran, Carissa <Cyran. Carissa@epa.gov>; Vogel, Dana <Vogel. Dana@epa.gov>;

Wilbur, Donald < Wilbur. Donald@epa.gov >; Reaves, Elissa < Reaves. Elissa@epa.gov >; Kiely, Timothy

<Kiely.Timothy@epa.gov>

Cc: Metzger, Michael < Metzger.Michael@epa.gov>; Feitel, Alexandra < feitel.alexandra@epa.gov>; Pyne, Jaclyn

<Pyne.Jaclyn@epa.gov>

Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

I agree with Anna

From: Lowit, Anna < Lowit. Anna@epa.gov> Sent: Tuesday, August 24, 2021 11:09 AM

To: Cyran, Carissa < Cyran. Carissa@epa.gov>; Vogel, Dana < Vogel. Dana@epa.gov>; Wilbur, Donald

<Wilbur.Donald@epa.gov>; Reaves, Elissa <Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>

Cc: Metzger, Michael <Metzger.Michael@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Feitel, Alexandra

<feitel.alexandra@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>

Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Based on conversations on the rule, I don't think

Ex. 5 Deliberative Process (DP)

From: Cyran, Carissa < Cyran. Carissa@epa.gov> Sent: Tuesday, August 24, 2021 11:08 AM

To: Vogel, Dana < Vogel. Dana@epa.gov>; Wilbur, Donald < Wilbur. Donald@epa.gov>; Reaves, Elissa

<Reaves.Elissa@epa.gov>; Kiely, Timothy <Kiely.Timothy@epa.gov>

Cc: Lowit, Anna <Lowit.Anna@epa.gov>; Metzger, Michael <Metzger.Michael@epa.gov>; Friedman, Dana

<Friedman.Dana@epa.gov>; Feitel, Alexandra <feitel.alexandra@epa.gov>; Pyne, Jaclyn <Pyne.Jaclyn@epa.gov>

Subject: Re: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Thank you, Elissa, Dana and Anna. We

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) Are you ok with the highlighted text?

# Ex. 5 Deliberative Process (DP)

## Ex. 5 Deliberative Process (DP)

From: Vogel, Dana < Vogel.Dana@epa.gov > Sent: Tuesday, August 24, 2021 11:05 AM

To: Cyran, Carissa < Cyran. Carissa@epa.gov>; Wilbur, Donald < Wilbur. Donald@epa.gov>; Reaves, Elissa

<<u>Reaves.Elissa@epa.gov</u>>; Kiely, Timothy <<u>Kiely.Timothy@epa.gov</u>>

Cc: Lowit, Anna <<u>Lowit.Anna@epa.gov</u>>; Metzger, Michael <<u>Metzger.Michael@epa.gov</u>>; Friedman, Dana <<u>Friedman.Dana@epa.gov</u>>; Feitel, Alexandra <<u>feitel.alexandra@epa.gov</u>>; Pyne, Jaclyn <<u>Pyne.Jaclyn@epa.gov</u>> Subject: RE: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

No comments from me.

From: Cyran, Carissa < Cyran.Carissa@epa.gov > Sent: Tuesday, August 24, 2021 10:34 AM

**To:** Vogel, Dana < <u>Vogel.Dana@epa.gov</u>>; Wilbur, Donald < <u>Wilbur.Donald@epa.gov</u>>; Reaves, Elissa < Reaves.Elissa@epa.gov>; Kiely, Timothy < Kiely.Timothy@epa.gov>

**Cc:** Lowit, Anna <<u>Lowit.Anna@epa.gov</u>>; Metzger, Michael <<u>Metzger.Michael@epa.gov</u>>; Friedman, Dana <<u>Friedman.Dana@epa.gov</u>>; Feitel, Alexandra <<u>feitel.alexandra@epa.gov</u>>; Pyne, Jaclyn <<u>Pyne.Jaclyn@epa.gov</u>>

Subject: FOR PRD and HED IO REVIEW: Press Inquiry The Intercept re: chlorpyrifos; DDL: 11:00 a.m. today

Importance: High

Good morning,

For your review, below is a draft response staff have pulled together. Please let me know if you have any comments/edits by 11:00 a.m. today.

### **INCOMING:**

If you would like to comment on any of the following, please send me your comments by noon tomorrow.

The agency's 2016 risk assessment recognized epidemiological studies that showed that the pesticide had lasting effects on children's brains, including those done by Virginia Rauh

Instead of relying on the work by Rauh and others looking directly at human effects, the latest decision on chlorpyrifos used a less sensitive endpoint - the depression of cholinesterase activity.

"EPA could have used the human evidence," said Tracey Woodruff, director of the Program on Reproductive Health and the Environment at the University of California, San Francisco. "But they actually walked back what they did in 2016."

"They are just creating barriers to using these studies," said Woodruff, who said she believed that industry capture within the pesticide program as the source of the problem.

Patti Goldman, an attorney for Earthjustice, told me that "You can bet the chemical companies are going to work on these models as fast as they can now," she said. "They'll try to get EPA to say, 'Oh, let's pinpoint the exposure that causes 10

percent cholinesterase inhibition," the cutoff now used. "And if that happens, children would be exposed to levels that damage their brains."

Goldman told me that she fears the reliance on the cholinesterase endpoint in the chlorpyrifos decision could be used in the upcoming assessments of the 15 other organophosphate pesticides now used on food to potentially allow them to stay in use.

### RESPONSE:

# Ex. 5 Deliberative Process (DP)

From: Vogel, Dana < Vogel.Dana@epa.gov>
Sent: Tuesday, August 24, 2021 8:09 AM

To: Reaves, Elissa <<u>Reaves.Elissa@epa.gov</u>>; Ozmen, Shamus <<u>Ozmen.Shamus@epa.gov</u>>; Messina, Edward <<u>Messina.Edward@epa.gov</u>>; Goodis, Michael <<u>Goodis.Michael@epa.gov</u>>; Lowit, Anna <<u>Lowit.Anna@epa.gov</u>> Cc: Cyran, Carissa <Cyran.Carissa@epa.gov>; Friedman, Dana <Friedman.Dana@epa.gov>; Wilbur, Donald

<Wilbur.Donald@epa.gov>

Subject: RE: heads up -before 11am FW: OPS: Sharon Lerner - chlorpyrifos

+ Anna

From: Reaves, Elissa < Reaves. Elissa@epa.gov > Sent: Tuesday, August 24, 2021 8:07 AM

**To:** Ozmen, Shamus < <u>Ozmen.Shamus@epa.gov</u>>; Messina, Edward < <u>Messina.Edward@epa.gov</u>>; Goodis, Michael < Goodis.Michael@epa.gov>

**Cc:** Cyran, Carissa < <u>Cyran.Carissa@epa.gov</u>>; Vogel, Dana < <u>Vogel.Dana@epa.gov</u>>; Friedman, Dana < <u>Friedman.Dana@epa.gov</u>>

Subject: RE: heads up -before 11am FW: OPS: Sharon Lerner - chlorpyrifos

Looping in HED given the thread below.

Elissa Reaves, Ph.D.
Director, Pesticide Re-evaluation Division
Office of Pesticide Programs
703-305-0312

From: Ozmen, Shamus < Ozmen. Shamus@epa.gov>

Sent: Tuesday, August 24, 2021 8:05 AM

To: Messina, Edward < Messina. Edward@epa.gov >; Goodis, Michael < Goodis. Michael@epa.gov >; Reaves, Elissa

<Reaves.Elissa@epa.gov>

Cc: Cyran, Carissa < Cyran. Carissa@epa.gov>

Subject: heads up -before 11am FW: OPS: Sharon Lerner - chlorpyrifos

We are working on this but wanted to flag that a rapid review will be coming to you shortly.

From: Dunton, Cheryl < Dunton. Cheryl@epa.gov >

Sent: Tuesday, August 24, 2021 6:02 AM

To: Cyran, Carissa < Cyran. Carissa @epa.gov >; Ozmen, Shamus < Ozmen. Shamus @epa.gov >

Subject: FW: OPS: Sharon Lerner - chlorpyrifos

I'd like to get a response by 11 am to make Sharon's noon deadline. Michal wants to make sure we note that the court gave us 60 days to act.

From: Daguillard, Robert < Daguillard.Robert@epa.gov>

Sent: Monday, August 23, 2021 6:09 PM

To: OPS CSID CB < OPS CSID CB@epa.gov>; Dunton, Cheryl < Dunton. Cheryl@epa.gov>

**Cc:** Labbe, Ken < <u>Labbe.Ken@epa.gov</u>> **Subject:** OPS: Sharon Lerner - chlorpyrifos

Good evening team. Sharon's latest.

Best as always, R.

Hi Nick, Robert and the Press office-

We are running a piece on chlorpyrifos and have the follow points for you to review. If you would like to comment on any of the following, please send me your comments by noon tomorrow.

Thank you,

Sharon

The agency's 2016 <u>risk assessment</u> recognized epidemiological studies that showed that the pesticide had lasting effects on children's brains, including those done by Virginia Rauh

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Sharon Lerner
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PGP:

CB29 D9FF 9285 3205 087E 83A1 0C30 2F39 4F30 8BFE